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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/076,131	02/13/2002	Babu J. Mavunkel	219002028310	9859
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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/04/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,131

Applicant(s)

MAVUNKEL ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 39-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 39-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. This application is a divisional of SN 09/316,761. Claims 1-38 have been canceled. Claims 39-78 are pending.

2. Claims 39, 40, 42, 45-46, 49, 60, 63, 68-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 63, 68-71, the term "comprising" renders the claim indefinite because it is unclear whether the claim is further limiting or not since the term is improper in a Markush format and is ambiguous as to whether it is broadening the Markush elements for the variable. The term "comprising" in a Markush claim is improper. See MPEP 2173.05(h).

Regarding claims 39, 40, 42, 45-46, 49, 60, it is unclear "what" is the scope being embraced by the term "two R⁴ taken together form a bridge optionally containing a heteratom"; "CO or an isostere thereof"; "CH, CH₂ or an isostere thereof" or "Y is optionally substituted alkyl, optionally substituted aryl or optionally substituted aralkyl or two Y taken together may form an alkylene (2-3C) bridge".

There is insufficient descriptive basis for the term "two R⁴ taken together form a bridge optionally containing a heteratom" i.e. lacking specific description with starting material of making such optional compounds available. Given the broadest interpretation, such structure would include those recited in CHEMCATS 2002:1367700 which has been on market. Since the parent cases (see issued patents US 6,130,235 or US 6,340,685) showed that such compound was not disclosed, thus, the CHEMCATS reference would constitute a 102(a) or (f) reference of the instant CIP (02/13/02) and such rejection will follow in next section.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

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raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 39, 40, 42, 45-46, 49, 60, recite the broad recitation X¹ is "or an isostere thereof" and X² is "CH, CH₂ or an isostere thereof" and the claim also recites X¹ is "CO" and X² is "CH, CH₂" which is the narrower statement of the range/limitation. It is unclear "what" is the scope for these elements. Are they those variations numerated on page 3 or are they broadly encompassed all conventional isosteric structure (see CA 67:107052). If they are broadly encompassing all conventional isosteric structure and those disclosed on page 3, the 102 and 103(a) rejections will follow in next section.

It is unclear as to what the structure for "Y is optionally substituted alkyl, optionally substituted aryl or optionally substituted aralkyl or two Y taken together may form an alkylene (2-3C) bridge" is. If this is broadly encompassing non-single ring piperidine such as CA 135: 313624, then the 103(a) rejection will follow in next section.

3. Claims 39, 40, 42, 45-46, 49, 60, 75-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. As a correlated rejection of the above 112 second paragraph, the broad scope as delineated supra lacks antecedent basis as well as enabling description. Not only the compounds encompassed by the broad scope of the claims as found in the recited art was not described in the specification as originally filed or subsequent CIP, the starting material and how to make such compounds i.e. being encompassed by the scope "two R⁴ taken together form a bridge optionally containing a heteratom"; "CO or an isostere thereof"; "CH, CH₂ or an isostere thereof" or "Y is optionally substituted alkyl, optionally substituted aryl or optionally substituted aralkyl or two Y taken together may form an alkylene (2-3C) bridge", were not found in the specification. Those compounds embraced by the broad scope of the claims further evidenced that such compounds do not share the inventive utility as p-38 kinases inhibitor, see i.e. CA 131:676650.

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Please note that the invention is drawn to the highly unpredictable field in inhibiting enzyme using vary large numbers of compounds of unknown structure in order to treating conditions which is pro-inflammation for which the scope can not be ascertained i.e how "pro" is considered proinflammation. Therefore, lacking sufficient structural descriptive for the terms, lacking sufficient provision of source of starting material, and lacking any predictability of what chemical structure is inexorably linked to enzyme activity or its outcome, it was found that the specification lacks sufficient description commensurate with the scope of the claims.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 39, 40, 42, 45-46, 49, 60, are rejected under 35 U.S.C. 102(a) as being anticipated by CA 131:97650, CHEMCATS 2002:1367700 or CA 132:347492. Please note that it was explained supra that the parent cases (see issued patents US 6,130,235 or US 6,340,685) showed that such compound was not disclosed. Therefore, the instant claims being drawn to these compounds do not have the benefit of the priority filing, thus, the references supra would constitute prior art against the instant CIP (02/13/02).

See RN 228552-27-0 or RN 414893-18-8 or 268730-34-3.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 39, 40, 42, 45-46, 49, 60, are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 135:313624. Please note that it was explained supra that the parent cases (see issued patents US 6,130,235 or US 6,340,685) showed that such compound was not disclosed. Therefore, the instant claims being drawn to these compounds do not have the benefit of the priority filing, thus, the reference CA 135 would constitute prior art against the instant CIP (02/13/02).

Determination of the scope and content of the prior art (MPEP §2141.01)

Kafkaïen et al. Ca 135 disclosed the instantly claimed non-single ring piperidinyl compounds wherein a species has been exemplified as RN 367509-01-1.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the exemplified species and the claims is that the piperidinyl ring was linked to the indolyl ring at the 2-position while the claims are drawn to 5, or 6-position substitution.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One skilled in the art would be motivated to prepare a position isomer of the exemplified species since position isomerism has been recognized in the chemical art to be a close structural tool for obtaining more useful compounds. In re Englehard 208 USPQ 343. Especially, such position isomerism is generically taught with enabled examples in alternative heretocyclic analogues (see RN 367508-34-7 or 367510-05-2).

6. Claims 39-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,410,540, 6,448,257 or 2002/0115671. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Regarding US 6,410,540, please note that '540 claim 1, proviso out indolyl compounds for the method but the nonindolyl compounds reading on the instant claims 75-78 have been claimed.

Regarding US 6,448,257, please note that the claims reading on the instant claims with "bridge".

Regarding US 2002/0115671, please note that the claims are in nonstatutory "use" format but the exact compounds of the instant claims are found on page 9, for example (exhaust listing is not made here).

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The instant application and the issued patents . 6,410,540, 6,448,257 or 2002/0115671, although are commonly assigned, have "different inventive entity" with identical or overlapping subject matter with species and claims particularly identified supra.

In so far as the identical species/claims is concerned, since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

In so far as the overlapping subject matter is concerned, the nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

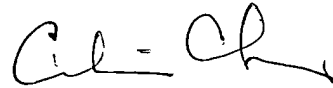
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

*OACS/Chang
April 2, 2002*

A handwritten signature in black ink, appearing to read 'Celia Chang', with a stylized flourish at the end.

*Celia Chang
Primary Examiner
Art Unit 1625*